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Dated: August 18, 2004

Signature: Shawn P. Foley
(Shawn P. Foley)

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Docket No.:
CELLTH 3.0-003 CONT CONT IV
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Warrell et al.

Application No.: 10/759,313

Group Art Unit: 1616

Filed: January 16, 2004

Examiner: A. N. Pryor

For: PROCESS FOR PRODUCING ARSENIC
TRIOXIDE FORMULATIONS AND
METHODS FOR TREATING CANCER USING
ARSENIC TRIOXIDE OR MELARSOPROL

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONSIDERATION OF INFORMATION UNDER 37 CFR § 1.97 (C)

Dear Sir:

It is respectfully requested that the references cited in the enclosed form be considered pursuant to 37 C.F.R. § 1.97(c). Please charge Deposit Account No. 12-1095 in the amount of \$180.00 pursuant to 37 C.F.R. § 1.17(p). In the event that any additional fee is due in connection with the present request, the same should be charged to our Deposit Account No. 12-1095.

Dated: August 18, 2004

Respectfully submitted,

By Shawn P. Foley
Shawn P. Foley
Registration No.: 33,071
LERNER, DAVID, LITTMERBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant



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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in United States Patent 6,723,351, the benefit of which is claimed under §120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

In the event that any fee is due in connection with the present Information Disclosure Statement, the Commissioner is hereby authorized to charge the same to our Deposit Account

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600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant

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Substitute for form 1449A/B/PTO				Complete if Known	
				Application Number	10/759,313
				Filing Date	January 16, 2004
				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	1	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT IV

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
AA**	US-132,275-B1	10-15-1872	Gettings		
AB**	US-232,807	10-05-1886	Dennett		
AC**	US-3,700,498	10-24-1972	Kanazawa et al.		
AD**	US-4,497,780	02-05-1985	Barin et al.		
AE**	US-5,759,837	06-02-1998	Kuhajda et al.		
AF**	US-2002/0183385	12-05-2002	Ellison et al.		
AG**	US-6,720,011	04-13-2004	Zhang, Ting-Dong		
AH**	US-6,770,304	08-03-2004	Warrell et al.		
AI**	US-2003/0099719	05/2003	Warrell et al.		
AJ**	US-6,723,351	04-20-2004	Warrell et al.		
AK**	US-6,773,792	05-11-2004	Lu		

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
BA	JP-51-88620		03-08-1976		
BB	WO-95/01789		01-19-1995		
BC	CN-1133725		10-23-1996		
BD	CN-1131037		09-18-1996		
BE	CN-1122700		05-22-1996		
BF	CN-1081104		01-26-1994		
BG	CN-1119113		03-27-1996		
BH	CN-1061908		06-17-1992		
BI	CN-1121807		05-08-1996		
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BK	WO-94/02103		02-03-1994		
BL	FR-2 539 993		03-31-1994		
BM	DE-43 17 331		12-01-1994		
BN	WO-95/22336		08-24-1995		
BO	LV-11667		06-20-1997		
BP	WO-94/02108		02-03-1994		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
CA	CUTLER et al., Article IV, American Journal of the Medical Sciences, pp. 74-84, January 1878				
CB	FORKNER et al., "Arsenic as a therapeutic agent in chronic myelogenous leukemia", Jour.				

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO

*Complete if Known***INFORMATION DISCLOSURE
STATEMENT BY APPLICANT***(Use as many sheets as necessary)*

Sheet 2 of 5 Attorney Docket Number CELLTH 3.0-003 CONT CONT IV

		A.M.A. 97(1):3-5, 1931	
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CD	NEUBAUER, "Arsenical cancer: a review", Arsenic Committee of the Medical Research Council, pp. 192-251, 1947		
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CC1	Chemical Abstract, 63-Pharmaceuticals 11:317, 111:219272] and 111:219276p, 1987-1991		

Examiner
SignatureDate
Considered

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				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	3	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT IV

	CD1	CHEN et al., "In Vitro Studies on Cellular and Molecular Mechanisms of Arsenic Trioxide (As ₂ O ₃) in the Treatment of Acute Promyelocytic Leukemia: As ₂ O ₃ induces NB ₄ Cell Apoptosis with Down Regulation of Bcl-2 Expression and Modulation of PML-RAR α /PML proteins", Blood 88(3): 1052-1061, Aug. 1996 ©American Society of Hematology 1996	
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	CK1	GERMOLEC et al., "Arsenic Induces Overexpression of Growth Factors in Human Keratinocytes", Toxicology and Applied Pharmacology, 141:301-318, 1996 ©Academic Press, Inc., 1996	
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	CS1	REICHL et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol., Suppl. 13, p. 363-65, 1989	
	CT1	Remington's Pharmaceutical Sciences, Mack Publishing Co., Easton, PA, pp. 1570-1580, 1990	
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Examiner Signature		Date Considered	
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				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	4	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT IV

	CB2	YUAN et al., "Research on Traditional Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):23-26, 1988	
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	CJ2	USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville, MD, p. 59, Nov. 1995.	
	CK2	WANG et al., "Arsenic and the Treatment of Leukemia", J Harbin Medical Univ., vol. 31, No. 5, Oct. 1997	
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	CR2	ZHANG et al., "Pathologic, Cytogenetic and Molecular Assessment of Acute Promyelocytic Leukemia Patients Treated with Arsenic Trioxide (As ₂ O ₃)", Modern Pathology; (2000); pp. 954-961	
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	CT2	SOIGNET et al.; "United States Multicenter Study of Arsenic Trioxide in Relapsed Acute Promyelocytic Leukemia", Journal of Clinical Oncology, (2001), vol. 19, No. 18, pp. 3852-3880	
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Examiner Signature		Date Considered	
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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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